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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,313	11/28/2000	Elmar Reinhold Burchardt	LeA 32 701	8752

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/701,313	BURCHARDT ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-5 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)).

For examination purposes "use" claims are interpreted as a method of the first recited "use".

2. It is not clear whether claim 5 as an immunoassay method or an immunoassay product, given the apparent ambiguity about the claimed immunoassay, claim 5 has been limited to either an immunoassay method or an immunoassay product, irrespective of the format of the claim. Due to the ambiguity, the "immunoassay" has been placed in both Groups. Applicant is required to state whether claim 5 is drawn to a method or a product.

3. The specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. Page 6, line 24, page 7, line 12, page 29, Table 1, lines 10, 11, 16, 17, 23, 24, 30 and 31 and page 30, Table 2, lines 3-10 have described several amino acid and nucleic acid sequences that each must have a sequence identifier. Correction is required.

4. Claim 3 is objected to under 37CFR 1.821(d) for failing to recite the SEQ ID NO in the claim.

5. Claims 1-5 are objected to because they contain several periods "." in the middle of the claims. Further, the term "described in 1. and 2." and "described in 3." should refer to "claim 1 and claim 2" and "claim 3", respectively. In addition, the claims should refer to other claims in the alternative "or" rather than "and". Finally, the claims should have an article in front of the preamble.

Election/Restrictions

6. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

7. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-3 and 5, drawn to a monoclonal antibody directed against an epitope within the 30 most N-terminal amino acids of human PIIINP, or an oligopeptide with the sequence derived from the N-terminal peptide is of Col2 domain of PIIINP.

II. Claims 4-5, drawn to a method a sandwich immunoassay that detects intact PIIINP using the anti-PIIINP antibodies.

8. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Brocks and Timple (see entire document).

Brocks and Timple teach a polyclonal antibodies against the amino-terminal of procollegen peptide (type III) with the sequence ICESCPTGGQNYSP from the Col2 domain of PIIINP, which cleaved off outside the cell after secretion of procollegen (type III) molecule. Further, the '210 publication teaches that the concentration of this procollegen peptide in the body fluids can be determined using antibodies against the procollegen peptide (see page 1, lines 5-8, page 2, lines 18-26, Example 2, and published claims 1-10 in particular). Brocks and Timple teach accurate selective determination of procollagen peptide (type III) in serum and other body fluids is not possible using the methods described in the prior art because the polyclonal antibodies which are used in these methods react, with different, lower affinity, with various antigens which occur in serum and some of which are breakdown products of procollagen peptides (type III) (see page 1, lines 15-20. The referenced peptide sequence is amino acid residues 8-21 of claimed Col2 domain of PIIINP.

The claimed invention differs from the reference teachings only by the recitation of monoclonal antibodies that specifically binds the in claim 3.

However, it has been held that once the antigen of interest is selected, the use of that antigen in the known method of Kohler and Milstein will result in the expected hybrid cell lines and the specific monoclonal antibodies. Ex parte Erlich, 3 USPQ2d 1011, 1015 (BPAI 1986).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

9. The application contains claims directed to the following patentably distinct species of the claimed Invention I: wherein monoclonal antibody against:

A. the 30 most N-terminal amino acids of human PIIINP or
B. the N-terminal peptide of the Col2 domain.

These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad

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February 20, 2007